UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/535,390	03/24/00	GHOSH B	U 012673-3

HM12/0118

WILLIAM R EVANS
LADAS & PARRY
26 WEST 61 STREET
NEW YORK NY 10023

EXAMINER	
KWON, B	

ART UNIT	PAPER NUMBER
1614	4

DATE MAILED: 01/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/535,390	GHOSH ET AL.	
	Examiner	Art Unit	
	Brian-Yong S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites a method of treating septic shock condition, but each method steps in claim 2 teach a laboratory diagnostic procedure for confirming the activity of curcumin on LPS induced septic shock. It is noted that applicants have clearly failed to further limit the preamble of the claim. It is suggested that "a method for diagnosing septic shock conditions in animal..." should be recited.

2. Regarding claim 2, the phrase " preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Aggarwal (WO 9709877).

Aggarwal teaches in claim 1, "a method of inhibiting the activation of the NF-kB treanscription factior in animal in need of such treatment comprising the step of administering to said animal a pharmacologically effective dose of curcumin; in claim 2, " the method of claim 1, wherein said animal is a human; and in claim 3, "the method of claim 2, where said human has pathophysiological state selected from the group consisting of toxic/septic shock...".

Aggarwal inherently teaches "at once envisage", in view of claims 1-3, the use of curcumin in treating septic shock. See *In re Peterin, 301 F.2d 676, 133 USPQ 275 (CCPA).* It is also noted that a claim is anticipated if each and every element as set forth in the claim is found inherently described. See *Ex parte Novitski 126 USPQ 1389 (BOPA 1993).*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aggarwal (WO 9709877) in view of Majeed et al. (US 5861415) and Lai et al. (US 6093743).

Aggarwal (WO 9709877) teach a use of curcumin in treating septic shock, wherein said curcumin is administered in a dose of from about 1mg/kg to about 100mg/kg (see from page 1 line 21 to page 2 line 2 as well as claim 1and 3). However, Aggarwal fails to teach the use of curcumin in treating LPS induced septic shock conditions as well as monitoring the activity of curcumin in treating said conditions by observing septic shock symptoms and probing the reduction in neutrophil infiltration from blood vessels to the underlying tissue.

Majeed et al. (US 5861415) teach that curcumin inhibits lipopolysaccharide (LPS) induced nitrite production that is converted from nitric oxide: See column 2, lines 32-33.

Lai et al. (US 6093743) teach that the overproduction of nitric oxide causes various disease including septic shock (see column 1 line 60-65); the activity of curcumin as a nitric oxide scavenger (see column 20, line 60); and the active ingredients such as curcumin can be

formulated with non-toxic, pharmaceutically acceptable solvents or oils (see from column 34 line 4 to column 35 line 3) and antioxidants (see column 35, lines 3-5) for treating various diseases including septic shock.

It would have been obvious to a person skilled in art to combine the teachings of above references to produce a pharmaceutical composition that treat LPS induced septic shock conditions or septic shock since Aggarwal relate to the use of curcumin in treating septic shock; Majeed et al. relate to the use of curcumin in inhibiting lipopolysaccharide (LPS); and Lai et al. relate to the overproduction of nitric oxide causes various disease including septic shock and the activity of curcumin as a nitric oxide scavenger. The above references in combination make clear that the use of curcumin in treating LPS induced septic shock conditions or septic shock is old and well known. The teachings of Majeed and Lai et al. also clearly support that one having ordinary skilled in the art would have expected to use known nitric oxide scavenger such as curcumin to inhibit the overproduction of nitric oxide which has been induced by LPS and subsequently utilize curcumin in treating septic shock.

The prior art does not disclose time interval requirement for the initial and subsequent dose of curcumin which is administered prior to and after the said injection of LPS. However, differences in time interval requirements will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such time periods is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable time periods by routine experimentation.

6. With respect to claims 7 and 8, the modified method of Aggarwal includes all that is recited in these claims except for the optional use of antioxidant with curcumin in non-toxic, pharmaceutically acceptable solvents or oil. Lai et al. (US 6093743) teach that the active ingredients such as curcumin can be formulated with non-toxic, pharmaceutically acceptable solvents or oils (see from column 34 line 4 to column 35 line 3) and antioxidants (see column 35, lines 3-5) for treating various diseases including septic shock.

It would have been obvious to a person skilled in art to further modify the modified method of Aggarwal such that secondary ingredients can be added to the claimed type composition. One having ordinary skill in art would have expected that adding secondary ingredient to curcumin composition in a pharmaceutically acceptable carrier would have been determined in the prior art method.

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-8 are properly rejected under 35 U.S.C. 103.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mariann Cintins, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

MARIANNE M. CINTINS
SUPERVISORY PATENT EXAMINER
GROUP 120